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- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
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Published:

with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CONTROLLED RELEASE PHARMACEUTICAL COMPOSITIONS OF CARBIDOPA AND LEVODOPA

(57) Abstract: The present invention relates to controlled release pharmaceutical compositions of carbidopa and levodopa that include a combination of different molecular weight cellulose ethers and in particular, hydroxypropyl cellulose ether.

INTERNATIONAL SEARCH REPORT

Ir nal Application No PCT 03/01361

A. CLASSIFICATION OF SUBJECT MATN IPC 7 A61K9/22 A6

A61K31/195

A61P25/16

//(A61K31/195,31:195)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE, CHEM ABS Data

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 91 16885 A (ALZA CORP) 14 November 1991 (1991-11-14)	1,2,4, 8-17, 19-22, 24,25
	page 8, last paragraph page 9, line 19 - line 23 example 3	
x	WO 01 19349 A (SEN HIMADRI ;RAMPAL ASHOK (IN); RANBAXY LAB LTD (IN); RAGHUVANSHI) 22 March 2001 (2001-03-22)	1,2,4, 8-17, 19-22, 24,25
	page 3, line 14 -page 4, line 9 examples 1-5	
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X Fur	her documents are listed in the continuation of box C.	Patent family members are listed in annex.
'A' docum consi 'E' earlier filling 'L' docum which citatie 'O' docum other	ent defining the general state of the art which is not dered to be of particular relevance document but published on or after the international date ent which may throw doubts on priority claim(s) or is cited to establish the publication date of another on or other special reason (as specified) ment referring to an oral disclosure, use, exhibition or means ent published prior to the international filing date but than the priority date claimed	 "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family
Date of the	actual completion of the international search	Date of mailing of the international search report
;	3 July 2003	11/07/2003
Name and	mailing address of the ISA	Authorized officer
	European Patent Office, P.B. 5818 Patentlaan 2 NL 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	VON EGGELKRAUT, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

In all Application No
PCT 03/01361

	TO DE DEL SVANT	03/ 01301
	ation) DOCUMENTS CONSIDERS TO BE RELEVANT	Relevant to claim No.
Category °	Citation of document, with indication, where appropriate, of the relevant passages	
P,A	EP 1 262 198 A (PHARMA PASS S A) 4 December 2002 (2002-12-04) paragraph '0023! - paragraph '0026! example 1	1–7
A	EP 0 413 061 A (ALZA CORP) 20 February 1991 (1991-02-20) column 5, line 1 -column 6, line 10 examples 1,10-15	1–26
A	EP 0 440 462 A (MERCK & CO INC) 7 August 1991 (1991-08-07) claims 1-7	1–26
А	US 6 103 263 A (CHEN CHIH-MING ET AL) 15 August 2000 (2000-08-15) cited in the application column 1, line 54 - line 65	1-26
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Box I	Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)
This Inte	mational Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. χ	Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely: Although claims 21-26 are directed to a method of treatment of the
	human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2.	Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
. 🗀	
3	Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box II	Observations where unity of invention is lacking (Continuation of item 2 of first sheet)
This Inte	ernational Searching Authority found multiple inventions in this international application, as follows:
1.	As all required additional search fees were timely pald by the applicant, this international Search Report covers all searchable daims.
2.	As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.	As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.	No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Rema	The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1998)

INTERNATIONAL SEARCH REPORT

Ir nai Application No PCT 18 03/01361

					_	
Patent document cited in search report		Publication date		Patent family member(s)		Publication date
WO 9116885	Α	14-11-1991	US	5190763	Α	02-03-1993
MO 3110992	A	14-11 1991	AT	113203		15-11-1994
			AU	641770		30-09-1993
						27-11-1991
			AU		A	
			CA	2041579		08-11-1991
			DE	69104830		01-12-1994
			DΕ	69104830		02-03-1995
			DK	527835		18-04-1995
			EP	0527835	A1	24-02-1993
			ES	2067231	T3	16-03-1995
			FI	925029	Α	06-11-1992
			ΙĒ	911466		20-11-1991
			ĴP	2634322		23-07-1997
			JP	5506858		07-10-1993
			KR	169146		15-01-1999
						09-11-1992
			NO	924209		
			NZ	238011		21-12-1995
			NZ	248491		21-12-1995
			PT	97552		31-01-1992
			US	6217905	B1	17-04-2001
			WO	9116885	A1	14-11-1991
			US	5221536	Α	22-06-1993
		•	US	5192550		09-03-1993
			ZA	9103282		26-02-1992
WO 0119349		22-03-2001	AU	6589200	Α	17-04-2001
			CN	1402631	T	12-03-2003
			WO	0119349	A2	22-03-2001
EP 1262198	A	04-12-2002	US	2002192290	A1	19-12-2002
2. 1202100	••		ΕP	1262198	A1	04-12-2002
EP 0413061	Α	20-02-1991	US	4871548	Α	03-10-1989
0.13001	••		EP	0413061		20-02-1991
			ES	2069588		16-05-1995
EP 0440462	A	07-08-1991	US	5009895	Α	23-04-1991
LI UTTUTUL	,,	J. JJ 2552	CA	2035333		03-08-1991
			DE	69106154		09-02-1995
			DE	69106154		08-06-1995
				0440462		07-08-1991
			EP			
			JP 	7053364	-A	28-02-1995
US 6103263	Α	15-08-2000	NONE			